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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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07/21/2005

Katja Berg-Schultz

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9534

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7590

05/01/2009

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EXAMINER

MAEWALL, SNIGDHA

ART UNIT

PAPER NUMBER

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,927	<b>Applicant(s)</b> BERG-SCHULTZ ET AL.	
	<b>Examiner</b> Snigdha Maewall	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/19/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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### DETAILED ACTION

1. Receipt of Applicant's Arguments/Remarks and amended claims filed on 01/13/09 are acknowledged.

Claims 1-18 have been cancelled and new claims 19-26 have been added in this application.

Accordingly claims **19-26** are under prosecution.

The following rejections are maintained and are applicable to new claims **19-26**.

#### **Double Patenting (maintained rejection)**

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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3. Claims 19-26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1, 3 and 20 of copending Application No. 11/666666, in view of Lapidot (WO 00/71084).

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same sunscreen composition. The composition claimed in instant application is drawn to a cinnamate derivative encapsulated in a topical sunscreen, and at least one non-encapsulated UVA/UVB sunscreen with, for example, butyl methoxydibenzoylmethane, while the co-pending application (11/666666) is drawn to a sunscreen with UVA/UVB absorption using cinnamates and dibenzoyl methanes as sunscreen actives. Claims 1, 3 and 20 of copending application contain a sunscreen composition, with UVA and UVB absorption (see claim 1) with active ingredients of cinnamates and dibenzoylmethanes (see claims 3 and 20).

What is lacking in copending claims of 11/666666 is the teaching of encapsulation of at least one sunscreen active.

The teachings of Lapidot have been discussed above. Lapidot discloses encapsulating at least one sunscreen active in order to prevent photodegradation and cross reaction of actives while combined together in a composition.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Lapidot and the co-pending application 11/666666, to result in the claimed invention of 10/542927, with a reasonable expectation of success. One would have been motivated to combine the teachings of Lapidot and copending application

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11/666666 because Lapidot teaches the encapsulation of the sunscreen actives improves photo-stability of the composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Response to Arguments***

4. Applicant's arguments filed 01/13/09 have been fully considered but they are not persuasive.

Applicants argue that copending application has nothing in common with the present invention. The copending Application relates to covalently bound chromophores selected from cinnamates and the present invention relates to UV-absorbing cinnamate derivative which is encapsulated. As such the double patenting rejection shall be withdrawn.

Applicant's arguments are carefully considered but are not persuasive because the chromophores that the copending application is referring to are also cinnamates which has been claimed as UV absorbers in the instant invention. The only difference between the copending application and the instant application is that the instant cinnamate is encapsulated. The secondary reference teaches encapsulating the sunscreen agent in order to avoid photo degradation; as such it would have been obvious to one of ordinary skill in the art at the time of instant invention to encapsulate the cinnamate of copending reference and come to the claimed invention with a reasonable expectation of success. The rejection is therefore maintained.

**Claim Rejections - 35 USC § 102 (Maintained Rejection)**

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 19-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Lapidot, et al. (WO 00/71084) referred to herein as “Lapidot.”

Lapidot discloses a method for obtaining photostable sunscreen compositions using butyl methoxydibenzoylmethane (other known names: 4-tert-butyl-4'-methoxydibenzoylmethane, Avobenzene, and BMDBM) as a sunscreen active, and 2-ethylhexyl-p-methoxycinnamate as another sunscreen active as a preferred sunscreen active (see page 1, under background, second paragraph and page 4, under summary, second paragraph) reading on the instant formula of instant claim 23 and the instant elected species (2-ethylhexyl4-methoxycinnamate) claimed in present claim 24.

In one of the embodiments, Lapidot discloses a method of microencapsulating at least one of said active ingredients in an encapsulating material suitable for holding the active, and adding another active needed for preparation of said composition, see page 6, second paragraph. Lapidot discloses the sunscreen actives to be UVA and UVB absorbers (see page 4, summary), and the encapsulation of the sunscreen active as prepared by the sol-gel method, where the sunscreen agent is entrapped within a polymer matrix, resulting in the formation of a wall, prepared by the sol-gel silica method

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of micro-encapsulation (see page 8, third paragraph and Example 1) reading on instant claims 20-22.

Lapidot further discloses encapsulating only one or some of the active ingredients, while the other active ingredient(s) are present in the composition in a non-encapsulated form (see page 6, second paragraph).

Lapidot discloses that stabilization method is particularly efficient for stabilizing sunscreen formulations that contain octyl methoxycinnamate (OMC, 2-ethylhexyl-4-methoxycinnamate) or padimate with or without additional UVB absorbers such as 3, 3,5- trimethyl-cyclohexyl-salicylate (Homosalate) or 2-cyano-3, 3-diphenylacrylic acid, see page 6, last paragraph and page 7, first paragraph. The reference also teaches that several sunscreen agents may be co-encapsulated provided they do not cause photo degradation when in contact with each other, see page 7, first paragraph. The reference further teaches that inorganic sunscreen agents such as titanium dioxide or iron oxides are combined in a cosmetic composition in one of the preferred embodiments, see page 10, paragraph second. Example 2 depicts encapsulated sunscreen in silica and Imidazolidinyl urea as non- encapsulated sunscreen agent on page 11. Example 4 shows oil in water sunscreen composition containing encapsulated sunscreen actives such as OMC and Example 5 on page 13 shows titanium dioxide as non-encapsulated sunscreen agent.

### ***Response to Arguments***

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7. Applicant's arguments filed 01/13/09 have been fully considered but they are not persuasive.

Applicant argues that applicants' claims are patentable over Lapidot since it each fails to disclose each element of applicants' claims. Lapidot discloses a method for obtaining improved photostability of sunscreen compositions which contains at least two sunscreen active ingredients, which are photo-unstable when formulated together (p. 3, lines 8-10).

The Examiner notes and agrees with Applicant's assertion as one of the embodiments of the Lapidot's invention. However, the examiner recognizes that Lapidot discloses that in another embodiment the destructive reactions between two active agents are prevented by encapsulating only one or some of the active ingredients while other active ingredient/s are present in the composition in a non-encapsulated form see page 6, first paragraph under "DETAILED DESCRIPTION OF THE INVENTION".

Applicant argues that Lapidot discloses that photostability issues may occur when UVA filters are combined with UVB filters (page 1, lines 26-27). In particular Lapidot refers to the well known photo induced interaction of the UVA filter butylmethoxydibenzoylmethane (BMDBM) with the UVB absorber octyl methoxycinnamate (OMC) (page 1, paragraph 3). This cross reactivity contributes significantly to the photochemical instability of both the UVB and UVA active ingredients.

Applicant's arguments are considered but are not persuasive. The examiner notes that Lapidot discloses the photostability issues when UVA filters are combined



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with UVB filters, however, the reference also teaches that sol gel capsules are used to create barrier and the stabilization method is particularly efficient for stabilizing sunscreen formulations that contain octyl methoxycinnamate (OMC) see page 6, last 4 lines. The reference also teaches that encapsulation that holds the sunscreen active ingredients within the capsules and reduces or even prevents their leaching out, creates a barrier that reduces or even prevents cross reactivity, see page 6, fourth paragraph. Additionally the reference teaches that several active ingredients can be used provided they do not cause photodegradation when in contact, see page 6 first paragraph.

Applicant argues that additionally, Lapidot discloses that BMDBM (not the cinnamate derivative) undergoes photo induced interactions with physical sunscreen agents such as titanium dioxide or zinc oxide (page 2, second paragraph). The solution provided in Lapidot is to encapsulate one of the sunscreen active ingredients in order to avoid the cross reactivity. Lapidot contains, however no indication that encapsulated cinnamate derivatives itself exhibit a lack of stability upon irradiation (see the present application p. 1, lines 20-22 and example 1 on page 15, Table 2), i.e. that the cinnamate derivatives react with themselves within the shell resulting in a deactivation of the active ingredient. Furthermore, there is no indication in Lapidot how this stability problem of the encapsulated cinnamate derivative can be solved. Surprisingly, it has been found that the stability of the cinnamate derivatives within the shell can be significantly enhanced by the addition of an UV-B or a broad spectrum sunscreen. This is illustrated in example 1, Table 2 of the present invention: The addition of a UVB sunscreen such as e.g. 4-methylbenzylidene camphor or a broad spectrum sunscreen such as e.g. TiO<sub>2</sub>

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enhances the photostability of the encapsulated OMG from 35% to 60 % and more. The addition of a UVA sunscreen alone (i.e. avobenzene), however, only increases the photostability by to about 48%.

Applicant's arguments are considered but are not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the cinnamate derivatives react with themselves within the shell resulting in a deactivation of the active ingredient. Furthermore, there is no indication in Lapidot how this stability problem of the encapsulated cinnamate derivative can be solved) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Regarding photostability, Lapidot discloses that in order to avoid **photodegradation** by cross reaction of active agents, one or more of the active agents are **encapsulated**, therefore applicants assertion that Lapidot contains no stability indication for encapsulated cinnamate is not persuasive. The claims as recited do not define any percentage of photostability enhancement as argued by applicants. The rejection will be maintained.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612